IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

LISA GAYLE BUTLER and DAVID A. HOLLAND, Individually and as Personal Representatives of the ESTATE OF MATY GAYLE HOLLAND, Deceased,	§	
Plaintiffs,	§	
v.	§	Case No. 4:18-cv-00898
JUNO THERAPEUTICS, INC.,	§	
Defendant.	§	

DEFENDANT JUNO THERAPEUTICS, INC.'S MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT PURSUANT TO FED. R. CIV. P. 12(B)(6)

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Defendant Juno Therapeutics, Inc. ("Juno") files its Motion to Dismiss Plaintiffs' Amended Complaint for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6), and in support thereof respectfully states as follows:

STATEMENT OF THE NATURE AND STAGE OF PROCEEDING

The Estate of Maty Gayle Holland and her parents, Lisa Gayle Butler and David A. Holland, filed the initial complaint in their wrongful death and survival act lawsuit against Juno on March 22, 2018. The lawsuit relates to Ms. Holland's enrollment and participation in the ROCKET trial, a Phase II clinical trial of an investigational immunotherapy known as JCAR015. Defendants moved to dismiss all counts on June 5, 2018, and, after response and reply briefs were submitted, the Court heard oral argument on September 5, 2018. Judge Rosenthal ordered Plaintiffs to file an amended complaint, subsequently denying Juno's motion to dismiss as moot. Dkt. 37 at 45; Dkt. 42. Plaintiffs filed the instant Amended Complaint on October 1, 2018. This is a motion to dismiss Plaintiffs' Amended Complaint under Fed. R. Civ. P. 12(b)(6).

SUMMARY OF ARGUMENT

All of Plaintiffs' claims against Juno—as the sponsor of the ROCKET trial—fail as a matter of law, and their new allegations cannot save any of their claims. Plaintiffs' strict liability claim for defective design fails because they do not allege the existence of any feasible "safer alternative design" for Juno's investigational drug JCAR015, as Texas law requires. Additionally, under Comment k of Section 402A, Restatement (Second) of Torts, design defect claims are inappropriate in cases involving investigational drugs in order to avoid a chilling effect on research and development of potentially life-saving medicines.

Plaintiffs also allege various claims based on strict liability, negligence, fraud, and breach of warranty. The crux of each of those claims, as Plaintiffs acknowledge, is Juno's alleged failure

to adequately warn Ms. Holland. They are barred for several independent reasons. First, under the learned-intermediary doctrine, pharmaceutical manufacturers like Juno owe no legal duty of disclosure directly to clinical trial participants. Their duty is to provide necessary information and warnings to the doctors—referred to as clinical trial investigators in the clinical trial setting—who administer the therapy. It is not disputed that Juno provided this to Ms. Holland's clinical trial investigators. Similarly, under federal regulations governing the administration of clinical trials, Juno—as a trial sponsor—owes no duty to warn the clinical trial participants.

Instead, the duty "to warn" is owed by the clinical trial investigators, who are required to obtain participants' informed consent. In this case, Plaintiffs concede Ms. Holland's clinical trial investigators provided her those warnings. Plaintiffs' failure to warn claims also fail under Texas law because they have failed to allege facts to rebut the statutory presumption of non-liability pursuant to Texas Civil Practice and Remedies Code § 82.007.

Plaintiffs have also failed to sufficiently plead facts supporting their claims based in negligence, fraud, and breach of warranty. Finally, because Plaintiffs' individual claims for exemplary damages are barred under the Texas Constitution and they have failed to state a claim for any of their causes of action pursuant to which such damages may be sought, their requests for exemplary damages should be stricken.

Accordingly, pursuant to Fed. R. Civ. P. 12(b)(6), Plaintiffs' claims against Juno should be dismissed in their entirety.

STATEMENT OF ISSUES

The issues to be ruled on in this motion are: (i) whether the Amended Complaint fails to state a cognizable claim for defective design; (ii) whether all of Plaintiffs' claims alleging a failure to warn fail as a matter of law; (iii) whether Plaintiffs failed to plead facts supporting their

negligence-based theories; (iv) whether Plaintiffs failed to state a cognizable claim for fraud or fraudulent concealment; (v) whether Plaintiffs failed to allege a valid claim for breach of warranty; and (vi) whether Plaintiffs' request for exemplary damages should be stricken.

STANDARD OF REVIEW

The purpose of the federal pleading requirements under Rule 8 of the Federal Rules of Civil Procedure is to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). To that end, a complaint must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id*. (citations omitted). The Supreme Court explained "[t]wo working principles underlie *Twombly*." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1940 (2009). First, courts need not accept as true "threadbare recitals of a cause of action's elements, supported by mere conclusory statements." *Id*. Second, courts must conduct a "context-specific" inquiry and rely on their judicial "experience and common sense" to determine whether a plaintiff's "well-pleaded factual allegations . . . plausibly give rise to an entitlement to relief." *Id*. at 1940–41.

In addition to meeting the plausibility standard, under Fed. R. Civ. P. 9(b), if a party is alleging fraud, the pleading must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009). The Fifth Circuit interprets Rule 9(b) strictly, "requiring a plaintiff pleading fraud to specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Herrmann Holdings Ltd. v. Lucent Techs. Inc*., 302 F.3d 552, 564–65 (5th Cir. 2002). Thus, Rule 9(b) generally requires the complaint to "set forth 'the who, what, when, where, and how' of the events at issue." *Dorsey v.*

Portfolio Equities, Inc., 540 F.3d 333, 339 (5th Cir. 2008) (quoting *ABC Arbitrage Plaintiffs Grp. v. Tchuruk*, 291 F.3d 336, 350 (5th Cir. 2002)).

FACTUAL BACKGROUND[1]

In August 2015, Juno's Phase II trial of JCAR015—referred to as the ROCKET trial—began. Amended Complaint ("Am. Compl.") at ¶ 42. According to the Amended Complaint, Ms. Holland enrolled in the ROCKET trial in May 2016 after learning that her Acute Lymphoblastic Leukemia ("ALL") had relapsed. *Id*. at ¶¶ 50-51. Plaintiffs allege that Ms. Holland's oncologist suggested she speak to a pediatric oncologist at MD Anderson Cancer Center ("MD Anderson") in Houston, Texas, and that the oncologist at MD Anderson advised Ms. Holland that she was potentially a candidate for the ROCKET Trial. *Id*. at ¶¶ 51-52.

Plaintiffs allege that, upon being presented with Ms. Holland's case, the leukemia team at MD Anderson, including Dr. William Wierda, the clinical trial investigator at MD Anderson, decided that Ms. Holland could be enrolled in the ROCKET Trial, pending additional pre-screening testing and her agreement to participate. *Id.* at ¶ 54. On May 16, 2016, after meeting with Dr. Wierda to discuss the ROCKET Trial, and being walked through the MD Anderson Informed Consent ("Informed Consent")[2] for the ROCKET Trial by Virginia Bayer, the Lead Clinical Research Nurse for the trial, Ms. Holland signed the Informed Consent. *Id.* at ¶¶ 55-57.

On June 15, 2016, more than a week prior to Ms. Holland being infused with any CAR-T cells, Dr. Wierda advised her of a recent patient death following a T cell infusion. *Id.* at ¶ 72. This

[1] The facts recited in this portion of the Motion are based largely upon the new allegations of Plaintiffs' Amended Complaint. For additional background, Juno refers the Court to the Factual Background Section of its initial motion to dismiss. *See* Dkt. 16 at 4-7.

[2] While Plaintiffs reference the Informed Consent as Exhibit 1 to their Amended Complaint, they only filed it with the Court as a separate attachment to their previous complaint. *See* Dkt. 6. Juno attaches the Informed Consent as Exhibit A to this Motion for the convenience of the Court.

patient death was allegedly due to cytokine release syndrome and neurotoxicity and had occurred at a different ROCKET trial site after Ms. Holland executed the Informed Consent. *Id.* at ¶ 68. Ms. Holland was specifically advised that this other clinical trial patient had developed a cerebral edema after his JCAR015 infusion. *Id*. at ¶ 72. Ms. Holland agreed to proceed with her participation in the clinical trial, and was infused with her genetically modified CAR-T cells on June 23, 2016. *Id*. at ¶ 77. Plaintiffs allege Ms. Holland later developed CRS and cerebral edema, passing away on June 30, 2016. *Id.* at ¶¶ 77-80.

ARGUMENT

Like Juno's previous motion to dismiss, this Motion seeks dismissal of each of the eight counts in Plaintiffs' complaint. The complaint was only amended to address Defendants' learned-intermediary argument (and remove Plaintiffs' negligence *per se* claim). All of the other allegations remain the same, and Plaintiffs' amendments do nothing to save their claims.

Count 1 (Wrongful Death) and Count 2 (Survival) are not stand-alone claims under Texas law. Rather, they require an underlying wrongful act by Juno. As fully set forth below, Plaintiffs' claims under Counts 3-8 are all deficient. Should the Court dismiss those counts, then Counts 1 and 2 also fail.

I. The Amended Complaint Does Not State a Claim for Defective Design (Count 3).

Plaintiffs' first substantive count, which is unchanged from their previous complaint, alleges that Juno is strictly liable due to JCAR015's alleged defective design and Juno's marketing defects. "In Texas,[3] section 402A of the Restatement (Second) of Torts governs claims for strict

[3] Plaintiffs do not dispute that Texas law applies to their claims. *See generally* Dkt. 25. In the unlikely event that Plaintiffs attempt to contest the choice of law in the future, Juno incorporates by reference its discussion of the "most significant relationship" test from its initial motion to dismiss. Dkt. 16 at 8.

liability in tort." *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997); *see also New Texas Auto Auction Servs., L.P. v. Gomez De Hernandez*, 249 S.W.3d 400, 402-403 (Tex. 2008). "A product may be proven to be defective if it is unreasonably dangerous in construction, or it is unreasonably dangerous as designed, or it is unreasonably dangerous because adequate warnings or instructions are not provided." *Lucas v. Texas Indus., Inc*., 696 S.W.2d 372, 377 (Tex. 1984); *see also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 381-82 (Tex. 1995).

Plaintiffs allege that JCAR015 was deficiently designed "because Juno's clinical trial participants exhibited an unjustifiable high rate of fatal side effects, including severe neurotoxicity and severe cytokine release syndrome." Am. Compl. at ¶ 99. This claim fails for two reasons. First, the Amended Complaint fails to allege any technologically and economically feasible safer alternative design for JCAR015, as is required under Texas common law. *See Gen. Motors Corp. v. Sanchez*, 997 S.W.2d 584, 588 (Tex. 1999) ("A plaintiff must prove that there is a safer alternative design in order to recover under a design defect theory."); *Merck & Co., Inc. v. Garza*, 277 S.W.3d 430, 440 (Tex. App.—San Antonio 2008) (similar), *rev'd on other grounds*, 347 S.W.3d 256 (Tex. 2011); *see also Gerber v. Hoffman-La Roche, Inc.*, 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005) ("Texas courts . . . require a plaintiff asserting a design defect cause of action to demonstrate 'that the defendant could have provided a safer alternative design.'" (quoting *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 (Tex. 1998))).

Plaintiffs attempt to plead a safer alternative design, alleging, "The severity and rate of JCAR015's side effects were much higher than those present in other studies, including Juno's competitors, such as Kite and Novartis, who have produced safer CAR-T immunotherapies that have received FDA approval." Am. Compl. at ¶ 99. But this bald assertion does not meet the pleading standards of *Twombly* and *Iqbal*. *See Rodriguez v. Gilead Scis., Inc.,* 2015 WL 236621,

at *3 (S.D. Tex. Jan. 16, 2015) ("Recognizing that a safer alternative design is a necessary element to a substantive design defect claim under Texas substantive law, federal procedural law requires that the pleading allege sufficient facts to support the plausibility of that element." (citing *Twombly*, 550 U.S. at 558)). It is not enough for Plaintiffs to allege that Juno should have used a different drug or combination of drugs or that alternate therapies were available to Ms. Holland; they must explain how JCAR015 could have been made safer. *See Brockert v. Wyeth Pharmaceuticals, Inc*., 287 S.W.3d 760, 770-71 (Tex. App.—Houston [14th Dist.] 2009, no pet.) (holding plaintiff's identification of a different drug was not a "safer alternative design," and thus insufficient to support a defective design claim). Simply alleging the existence of two other clinical trials involving CAR-T therapies does not cure the deficiency. *See, e.g.*, *Massa v. Genentech Inc*., 2012 WL 956192, at *7 (S.D. Tex. Mar. 19, 2012) (dismissing design defect claim where plaintiff merely "point[ed] to the existence of 'a number of competitive psoriasis treatments' on the market to demonstrate that 'Defendants always had the option of using an alternative chemical compound in their psoriasis treatment.'" (quoting plaintiff's complaint)). Therefore, Plaintiffs' design defect claim should be dismissed. *See Steen v. Medtronic, Inc.,* 2010 WL 2573455 at *2 (N.D. Tex. June 25, 2010) (dismissing design defect claim because the "[p]laintiff makes no factual allegations showing <u>how</u> the pacemaker was defectively designed and unreasonably dangerous" (emphasis in original) (internal quotes & citation omitted)).

Second, a design defect claim is generally inappropriate in cases involving experimental prescription drugs. Comment k of Section 402A recognizes that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) §402A, cmt. k. This is "true in particular of many new or <u>experimental drugs</u> as to which, because of lack of time and opportunity for sufficient medical

experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk." *Id*. (emphasis added). Thus, Plaintiffs' allegation that JCAR015 was defectively designed and unreasonably dangerous because it had "risks" fails as a matter of law. *See Gerber*, 392 F. Supp. 2d at 922 (dismissing design defect claim under comment k).

II. Plaintiffs' Claims Alleging a Failure to Warn Fail as a Matter of Law.

As Plaintiffs concede, their claims for strict liability (Count 3), fraud (Count 4), negligence (Counts 5, 6, 7), and breach of warranty (Count 8—mislabeled in the Amended Complaint as Count VII) are all based on Juno's alleged failure to adequately warn Ms. Holland. *See* Dkt. 25 at 5. While Plaintiffs have added some new, ultimately irrelevant details, the crux of these claims continues to be that the Informed Consent obtained from Ms. Holland omitted and affirmatively misrepresented information concerning JCAR015's side effects of severe neurotoxicity/cytokine release syndrome and a patient death during JCAR015's clinical trials. *See, e.g.*, Am. Compl. at ¶ 102. Crucially, Juno had no legal duty to warn Ms. Holland directly, and did not author, approve, or obtain the Informed Consent from Ms. Holland. The alleged duty that it had to warn the clinical trial investigators was satisfied by the information it provided in the Investigator's Brochure. As such, all of Plaintiffs' claims based on a purported failure to warn should be dismissed.

A. The Learned-Intermediary Doctrine

Where a plaintiff sues the manufacturer of a prescription drug for failing to adequately warn of the drug's effects, Texas courts employ the learned-intermediary doctrine. *Pustejovsky v. Pliva, Inc*., 623 F.3d 271, 276 (5th Cir. 2010). "The learned-intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn consumers." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 207 (5th Cir. 2008) (citing *Alm v. Aluminum Co. of*

Am., 717 S.W.2d 588, 591-92 (Tex. 1986)). "Texas law generally holds that the adequacy of a product's warning is a question of fact to be determined by the jury." *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006) (citations omitted). "In prescription drug cases involving the learned intermediary doctrine, however, when 'a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law.'" *Id.* (quoting *Rolen v. Burroughs Wellcome Co*., 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied)).

In *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012), the Texas Supreme Court explicitly held that the learned-intermediary doctrine applies in the context of prescription drugs. In doing so, it explained that "[p]rescription drugs are likely to be complex medicine esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers." *Id.* at 159 (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)). This rationale applies equally to investigational drugs, as the prescribing physician is still the one best suited to make decisions about treatment of a specific patient. As to exceptions to the learned-intermediary rule, the Texas Supreme Court declined to recognize any. *See id.*at 160 n.18. As such, the learned-intermediary doctrine applies, and Juno's alleged duty to warn was owed to the clinical trial investigators, not to Ms. Holland.[4]

[4] Courts have held that sponsors of a clinical trial owe no duty to the participants in the trial. In fact, a New York appellate court recently modified a lower court order to grant defendants' motion to dismiss as to claims that occurred during a clinical trial, holding that, "As the sponsors of a clinical trial, defendants owed no duty to plaintiff [], an enrollee in the trial." *Wholey v. Amgen, Inc.*, 2018 WL 4866993, at *1 (N.Y. App. Div. Oct. 9, 2018) (emphasis added) (citing *Sykes v. United States*, 507 Fed. Appx. 455, 462 (6th Cir. 2012); *Abney v. Amgen, Inc.*, 443 F.3d 540, 550 (6th Cir. 2006)). Similarly, courts have held that the learned-intermediary doctrine applies equally to investigational drugs. *See Tracy v. Merrell Dow Pharm*., 569 N.E.2d 875, 880 (Ohio 1991) (holding that learned-intermediary doctrine applied to drug being dispensed as part of investigational study); *see also Kernke v. Menninger Clinic, Inc.* 173 F. Supp. 2d 1117, 1122 (D. Kan. 2001) (granting summary judgment for manufacturer in Phase II clinical study wrongful death action where manufacturer provided adequate warnings to investigators in investigator's brochure); *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. Ct. App. 1978) ("In the case of prescription drugs (and

Here, Plaintiffs affirmatively allege that Juno provided the clinical trial investigators with warnings concerning the side effects of JCAR015 in the form of an Investigator's Brochure. Am. Compl. at ¶ 26. The Investigator's Brochure specifically warned of the risks and consequences of developing severe cytokine release syndrome ("sCRS") and neurotoxicity for adult B-cell ALL subjects who received CAR-T cells. *See* Investigator's Brochure[5] at 31-33, 35-44, 48-49 (attached hereto as Exhibit B).[6] Likewise, the Informed Consent which Plaintiffs allege Ms. Holland reviewed and executed also specifically warned of the risk of CRS and neurological side effects, and warned that these side effects could be fatal. *See* Informed Consent at 9-10.[7] Dr. Wierda was

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especially for investigational drugs, which can only be prescribed by selected physician investigators) the manufacturer's duty to warn is satisfied if proper warning is given to the prescribing physician.").

[5] Because Plaintiffs reference the Investigator's Brochure in the Amended Complaint, *see e.g.*, Am. Compl. ¶ 26, the Court can consider it in ruling on Juno's motion to dismiss. *See Grynberg v. BP P.L.C.*, 855 F. Supp. 2d 625, 639 (S.D. Tex. 2012), *aff'd,* 527 Fed. Appx. 278 (5th Cir. 2013) ("Generally, any documents that are referenced in the pleadings themselves may be considered [in a Rule 12(b)(6) motion]."); *see also Wilson v. Birnberg*, 569 F. App'x 343, 344 n.1 (5th Cir. 2014). Further, at the Motion Hearing before Judge Rosenthal on September 5, 2018, Plaintiffs conceded that the Investigator's Brochure was one of the documents the Court could properly consider in ruling on the motion to dismiss. *See* Dkt. 37 at 24-25.

[6] Warnings in the Investigator's Brochure included: "The most significant toxicities observed in adult B-cell ALL subjects who received CAR T cells have been sCRS and neurotoxicity. . . . CRS can manifest as fever, hypotension, rigors, altered mental status, and hypoxia, and it can be life-threatening." Investigator's Brochure at 31 (emphasis added). "Overall, sCRS was observed in seven of 33 (21%) treated subjects. In subjects with B-cell ALL, sCRS has been observed primarily in individuals with morphologic evidence of disease . . . at the time of cell infusion." *Id.* "Ten of 33 (30%) subjects evaluable for safety developed Grade 3/4 neurological toxicities." *Id.* "Severe and life-threatening toxicities may arise with CRS (i.e., sCRS), including cardiac toxicity, respiratory distress, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation." *Id.* at 39 (emphasis added). "Severe CRS, which may be life-threatening or fatal, has occurred in patients receiving 1928z CAR T cells." *Id.* at 48 (emphasis added). "Grade 3 or higher neurological toxicities occurred in approximately 30% of subjects following initiation of 1928z CAR T cell administration and included encephalopathy, convulsions, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders." *Id.* at 49.

[7] Warnings in the Informed Consent included: "[I]n some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death." Informed Consent at 9 (emphasis added). "This is an early study of JCAR015, so the side effects are not well known. . . . "[T]he study treatment may cause the following side effects:" "possible . . . organ failure . . . [and] changes in mental status, and/or seizure" and "cytokine release syndrome." *Id.* at 10.

further advised (and it is undisputed that he, in turn, advised Ms. Holland) of the death of a clinical trial patient who had developed life-threatening side effects of CRS and neurotoxicity after his JCAR015 infusion. Am. Compl. at ¶¶ 68, 72 (specifically alleging that Dr. Wierda informed Ms. Holland that "a patient had recently died after developing a high fever," and that the patient developed a cerebral edema). These allegations are particularly relevant in view of the Texas Supreme Court's holding in *Centocor*: "[W]hen the prescribing physician is aware of the product's risk and decides to use it anyway, any inadequacy of the product's warning, as a matter of law, is not the producing cause of the patient's injuries." 372 S.W.3d at 170.

Plaintiffs have argued that because Dr. Wierda was compensated for his work on the ROCKET Trial (*see, e.g.*, Am. Compl. ¶ 53), there essentially was no learned intermediary. But this is wrong both legally and factually. Texas courts have previously rejected arguments that compensation to physicians influences their treatment, or makes the learned-intermediary doctrine inapplicable. *See, e.g.*, *Baker v. Smith & Nephew Richards, Inc.*, 1999 WL 811334, at *24 (Tex. Dist. Ct. June 7, 1999) (ruling learned-intermediary doctrine applied despite allegations that manufacturer's regulatory misconduct influenced physician's treatment because of the fees he received), *aff'd sub nom. McMahon v. Smith & Nephew Richards, Inc.*, 2000 WL 991697 (Tex. App. July 20, 2000); *see also In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 706 (E.D. Tex. 1997) ("[I]f any physician allowed himself to become a mere conduit for [a manufacturer's] materials, then it is the physician who is responsible. By the same token, [a manufacturer] cannot remove a physician from the decision-making process, only the physician can do that by avoiding his responsibility to make an individualized balancing of the risk and benefits associated with a drug and to advise the patient of possible adverse reactions."), *aff'd*, 165 F.3d 374 (5th Cir. 1999). Other courts have routinely applied the learned-intermediary doctrine

where a doctor is compensated by a defendant drug manufacturer in the context of a clinical trial. *See, e.g.*, *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 880 (Ohio 1991) (applying the learned-intermediary doctrine even though the prescribing doctor received compensation for each participant added to study program).[8] Indeed, the duties of a clinical trial investigator are clearly delineated in the federal regulations, requiring investigators be "responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under [his or her] care; and for the control of drugs under investigation." 21 C.F.R. § 312.60. Such duties are not compromised merely because the investigator is being compensated for his expertise, time, and attention provided to the patients participating in the clinical trial.

Plaintiffs have previously relied on *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958 (S.D. Tex. 2012) and *Rodriguez*, 2015 WL 236621, but those decisions are distinguishable and founded on an ultimately inaccurate guess by the federal courts as to where Texas law was headed. In *Murthy*, the court's analysis was not singularly focused on the compensation of the doctor in declining to apply the learned-intermediary doctrine; instead, because plaintiff viewed a promotional video by the drug manufacturer, the court in *Murthy* said that the manufacturer "may have circumvented the doctor-patient relationship." *Murthy*, 847 F. Supp. at 971. There is no such allegation here—according to the Amended Complaint, the information Ms. Holland received was solely from the

[8] *See also Little v. Depuy Motech, Inc.*, 2000 WL 1519962, *8-9 (S.D. Cal. 2000) (applying the learned-intermediary doctrine and noting that physician's role as paid investigator in trials of such devices "further support[ed] a finding that [the physician] knew about the risks associated" with a particular medical device (emphasis added)). This is also true outside of the clinical trial context. *See In re Trasylol Prods. Liab. Litig.*, 2011 WL 2117257 (S.D. Fla. May 23, 2011) (granting summary judgment under learned-intermediary rule despite allegations that prescriber was biased because he was a consultant for defendant); *In re Zyprexa Prods. Liab. Litig.*, 2010 WL 348276, at *11 (E.D.N.Y. Jan. 22, 2010) (similar); *In re Vioxx Cases*, 2006 WL 6305292 (Cal. Super. Dec. 19, 2006) (similar, denying plaintiffs' motion for directed verdict).

MD Anderson leukemia team. *See, e.g.*, Am. Compl. ¶¶ 60, 71, 72. Moreover, *Murthy* was decided before the Texas Supreme Court's decision in *Centocor*, discussed above. Notably, the *Murthy* court incorrectly predicted that the Texas Supreme Court would affirm a lower court's rejection of the learned-intermediary doctrine in the context of direct to consumer marketing. *See Murthy*, 847 F. Supp. 2d at 970 (citing *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476, 499 (Tex. App.—Corpus Christi 2010, pet. granted)). In reversing the lower court and applying the learned-intermediary doctrine to the case before it, the Texas Supreme Court specifically noted the *Murthy* court's incorrect prediction. *See Centocor*, 372 S.W.3d at 162 n.22. The *Rodriguez* court merely followed the *Murthy* court. *Rodriguez*, 2015 WL 236621, at *6.[9]

Further, as Plaintiffs conceded at oral argument on the previous motion to dismiss, JCAR015 is prescribed through enrollment in the ROCKET Trial. Dkt. 37 at 35. Plaintiffs do not allege Ms. Holland was enrolled in the ROCKET Trial by Dr. Wierda alone, but rather by a team of investigators and other medical professionals. For example, Plaintiffs allege that it was Ms. Holland's oncologist who informed her of CAR-T immunotherapy, "which he described as 'the cutting edge,' and suggested she see a pediatric oncologist at MD Anderson, Dr. Michael E. Rytting." Am. Compl. ¶ 51. They allege that it was Dr. Rytting who informed Ms. Holland that there was an adult CAR-T trial for ALL that [she] could potentially be a candidate for, which [was] later [] identified as [the ROCKET Trial]." *Id.* ¶ 52. They allege that it was "the leukemia team at MD Anderson" that was presented with Ms. Holland's case, and "decided that [she] met the eligibility criteria and could be enrolled in the ROCKET Trial[.]" *Id.* ¶ 54. And, they allege it

[9] Other courts have declined to follow *Murthy*. *See, e.g.*, *Calisi v Abbott Labs.*, 2013 WL 5462274, at *3-4 (D. Mass. Feb. 25, 2013) (refusing to follow *Murthy* and rejecting any "physician compensation exception" to the learned-intermediary rule); *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 616 (S.D.N.Y. 2012) (similar).

was Virginia Bayer, MD Anderson's Lead Clinical Research Nurse, who "provided further information regarding the ROCKET Trial and answered Maty and her mother's questions," and "walked Maty and her mother through the ROCKET Trial Informed Consent[.]" *Id.* ¶ 57. After which, "Maty signed the form." *Id.* In fact, Plaintiffs affirmatively allege that, "Dr. Wierda was not a conduit for any warnings of the deadly risks of JCAR015 from Juno to Maty." *Id.* ¶ 58. Plaintiffs allege that all of these individuals were involved with the decision to enroll Ms. Holland in the ROCKET Trial, but do not allege that any of them—besides Dr. Wierda—were compensated by Juno. For this reason as well, the learned-intermediary doctrine should be applied to Plaintiffs' claims, regardless of whether Dr. Wierda received compensation.

Finally, Plaintiffs' arguments fail because they would amount to a *per se* rule that the learned-intermediary doctrine can never apply to clinical trials. This would remove from the equation the "medical expert, the prescribing physician [who] can take into account the propensities of the drug, as well as the susceptibilities of his patient." *See Centocor*, 372 S.W.3d at 159 (quoting *Reyes*, 498 F.2d at 1276). This cannot be correct as a policy matter, and would run counter to the governing Federal Regulations, 21 C.F.R. § 312.60, and the decision and reasoning in *Centocor*. Because the Texas Supreme Court has held that the learned-intermediary doctrine applies in the context of prescription drugs, *Centocor*, 372 S.W.3d at 157, and because the Investigator's Brochure as well as the Informed Consent and the investigator's subsequent patient conference explained the risks of the exact side effects which Plaintiffs allege caused Ms. Holland's injury, Juno's warnings were adequate as a matter of law. Thus, all of the allegations centering on an alleged failure to warn should be dismissed with prejudice.

B. Presumption of Non-Liability Under Texas Law

Wholly apart from the above-stated bases, and unaffected by Plaintiffs' new allegations, there is yet another reason why Plaintiffs cannot succeed on their claims that are based on an alleged failure to warn. They cannot overcome the statutory presumption under Texas law that pharmaceutical manufacturers are not liable for injuries allegedly caused by inadequate warnings if "the warnings or information that accompanied the product" were those approved by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended. Tex. Civ. Prac. & Rem. Code ("CPRC") § 82.007 states as follows:

> In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
> (1) the warnings or information that accompanied the product in its distribution were those approved by the [FDA]for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended . . . .

(emphases added).

The FDCA provides not only for FDA approval of drugs for marketing and sale to the general public, it also provides for FDA approval for the distribution of investigational new drug products in clinical trials such as the one in which Ms. Holland participated, the design of which had specifically been approved by the FDA. *See, e.g.,* 21 U.S.C. § 355; 21 C.F.R. § 312.23.[10] As

[10] Plaintiffs previously attempted to draw a distinction between the "authorization" granted by the FDA in order to commence a clinical trial, and "approval." Dkt. 25 at 17. Not only is it nonsensical (and alarming) to think that a drug manufacturer could commence a clinical trial involving human beings without first receiving the FDA's approval, there is no meaningful difference between the terms "authorization" and "approval." "Authorization" is defined as "[o]fficial permission to do something; sanction or warrant," while the term "approve" is similarly defined as "to give formal sanction to; to confirm authoritatively." Black's Law Dictionary (10th ed. 2014). Further, Section 82.007 is silent with respect to what level of approval is necessary to avail oneself of the section's protection, speaking only of products "approved under the Federal Food, Drug and Cosmetic Act (21 U.S.C. Section 301 et seq.)."

part of the IND application that must be approved by the FDA before commencing human clinical trials, a pharmaceutical manufacturer must submit for the FDA's review and approval "all labels and labeling" that will accompany the investigational drug, as well as the investigator's brochure that will be distributed to clinical investigators. *See* 21 C.F.R. §§ 312.23(5) (brochure), (7) (labeling). The investigator's brochure must contain, among other things, a "summary of the pharmacological and toxicological effects of the drug," "information relating to safety and effectiveness in humans obtained from prior clinical studies," and a "description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs, and of precautions or special monitoring to be done." *Id.* at § 312.23(5). Thus, the presumption of non-liability created by this statute is applicable in the context of an FDA-regulated clinical trial of a pharmaceutical product.

In *Murthy*, Judge Ellison, in ruling on a Rule 12(b)(6) motion to dismiss, considered the effect of the statutory presumption of CPRC Chapter 82 as applied to a patient's participation in a clinical trial, and held that the presumption applied to claims of strict liability, negligence, and breach of warranty, to the extent those claims were premised on an alleged failure to warn. 847 F. Supp. 2d at 977. Section 82.007 expressly precludes liability unless Plaintiffs can rebut the presumption by establishing one of four statutory exceptions. *See id.* § 82.007(b)(2)-(5). Plaintiffs do not—and cannot—allege facts that establish any of the exceptions and therefore their failure to warn claims must be dismissed. *See, e.g.*, *Murthy*, 847 F. Supp. 2d at 976-77 (granting motion to dismiss plaintiff's strict liability, negligence, and breach of warranty claims premised on failure to warn pursuant to § 82.007(a)).

III. Plaintiffs Fail to Plead Facts Supporting Their Negligence-Based Theories.

Independent from the fact that Plaintiffs' failure to warn claims fail as a matter of law, Plaintiffs have failed to sufficiently plead facts to support any of their negligence-based theories of liability. None of Plaintiffs' new allegations save their negligence-based claims.

A. Plaintiffs Fail to Allege a Plausible Claim of Negligence (Count 5).

"To state a claim for negligence in Texas, a plaintiff must show duty, breach, causation, and damages." *Morin v. Moore*, 309 F.3d 316, 326 (5th Cir. 2002) (citing *Ambrosio v. Carter's Shooting Ctr., Inc*., 20 S.W.3d 262, 265 (Tex. App.—Houston [14th Dist.] 2000, pet. denied)). Here, Plaintiffs allege that Juno owed duties to Ms. Holland that included "reasonable care in disclosing and warning of the reasonably known risks and side effects of JCAR015, designing JCAR015, and conducting the ROCKET trial." Am. Compl. at ¶ 103.[11]

With regard to Juno's duty to warn, Plaintiffs allege that Juno breached that duty by "failing to disclose to and warn Maty of the reasonably known risks and deadly side effects of JCAR015." *Id.* However, pursuant to the federal regulations, Juno did not owe a duty to warn to Ms. Holland; that duty belonged to the trial investigators. *See* 21 C.F.R. § 50.20 (placing the responsibility for obtaining informed consent with the investigator); *see also Gile v. Optical Radiation Corp*., 22 F.3d 540, 543 (3d Cir. 1994) (holding that informed consent is the duty of the physician and not the manufacturer); *Anderson v. George H. Lanier Mem. Hosp*., 982 F.2d 1513, 1516–17 (11th Cir. 1993) (same). Plaintiffs acknowledge as much in the Amended Complaint. *See, e.g.*, Am. Compl. at ¶ 26 ("With respect to patients in clinical trials, 'no investigator may involve a human being as

[11] To the extent this count can be read to assert a negligent design claim, Plaintiffs allege no facts as to how Juno breached its duty, and therefore, that claim must be dismissed. *See, e.g.*, *Velez v. Wells Fargo Bank, N.A.,* 2012 WL 13046844, at *4 (S.D. Tex. June 27, 2012) (dismissing plaintiffs' negligence claim because the defendant "[did] not have the opportunity to prepare a defense because they were not put on notice as to what facts are the basis for the Plaintiffs' claim of negligence").

a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject.' 21 C.F.R. § 50.20." (emphasis added)). This argument is also supported by the Informed Consent in this case from the investigator at MD Anderson, referred to in the document as the "Study Chair."

Plaintiffs also allege that Juno breached its duty when conducting the ROCKET trial by "establishing a study protocol for the ROCKET trial that permitted the administration of a drug with fatal side effects, including severe neurotoxicity and severe cytokine release syndrome." Am. Compl. at ¶ 103. But again, according to the FDA regulations, trial investigators are charged with the responsibility of "conducting" the clinical trial. *See* 21 CFR § 312.60 (stating that investigators are responsible "for protecting the rights, safety, and welfare of subjects under the investigator's care"). The regulations define an "investigator" as "an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject)." *Id*. § 312.3(b) (emphasis added). On the other hand, a sponsor—in this case, Juno—"does not actually conduct the investigation unless the sponsor is a sponsor-investigator." *Id*. (emphasis added). Plaintiffs admit in the Amended Complaint (as they did previously) that Juno was not a sponsor-investigator for the ROCKET trial. *See* Am Compl. at ¶ 53.

Plaintiffs' inappropriate attempts to shift liability to Juno, as the clinical trial sponsor, are analogous to *Kernke v. Menninger Clinic, Inc.*, where the plaintiffs alleged that Aventis—as the sponsor of a clinical trial—owed the decedent three duties: "(1) to determine whether the benefit to [decedent] in allowing him to participate in the M100907 drug study outweighed the risks to him in ingesting the drug; (2) to secure informed consent from [decedent]; and (3) to supervise [decedent] while he participated in the study." 173 F. Supp. 2d 1117, 1124 (D. Kan. 2001). However, the court granted Aventis's motion for summary judgment, because "all of the alleged

duties advanced by plaintiffs rest with the Menninger defendants as the investigators of the M100907 drug study, and not with Aventis as the sponsor of the study." *Id.*[12]

Because the purported legal duties Juno is alleged to have breached are not recognized under Texas law and because Plaintiffs admit—through both the Amended Complaint and the Informed Consent—that it is the investigators who owed duties to the decedent with respect to both the Informed Consent and Ms. Holland's general well-being while she was enrolled in the ROCKET trial, the Court should grant Juno's motion to dismiss all the negligence claims.

B. Plaintiffs Fail to Sufficiently Allege a Claim for Negligent Marketing (Count 6).

To prevail on a negligent marketing claim, a plaintiff is required to establish four elements: 1) a duty by defendant to act according to an applicable standard of care; 2) a breach of the applicable standard of care; 3) an injury; and 4) a causal connection between the breach of care and the injury. *See Ethicon Endo-Surgery, Inc. v. Gillies*, 343 S.W.3d 205, 211 (Tex. App.—Dallas 2011, pet. denied). Here, Plaintiffs allege that Juno breached its standard of care "by failing to disclose the reasonably known risks and side effects of JCAR015 to its investigators/agents and to its clinical trial patients." Am. Compl. ¶ 104.

As to the alleged duty owed to the trial investigators, Plaintiffs fail to allege any facts to support the conclusory assertion that Juno failed to inform investigators of the known risks and side effects of JCAR015. Indeed, Plaintiffs affirmatively allege that "Juno provided its investigators with an investigator's brochure and a sample/model form/proposed informed consent document for use in the ROCKET Trial that was required to describe the risks and side effects

[12] Similarly, in *Abney v. Amgen, Inc.*, 443 F.3d 540 (6th Cir. 2006), the court stressed the importance of limiting the legal duties of a pharmaceutical manufacturer: "[U]nder the FDA's regulatory scheme it is not the pharmaceutical companies that are charged with ensuring trial participants' well being. Rather, it is the Institutional Review Board that is meant to 'protect the rights and welfare' of trial participants during a clinical trial." *Id.* at 551 (citing 21 C.F.R. §§ 56.101, 56.103). *See also Wholey*, 2018 WL 4866993, at *1 ("As the sponsors of a clinical trial, defendants owed no duty to plaintiff [], an enrollee in the trial.").

associated with JCAR015." *Id.* at ¶ 26. Not only are Plaintiffs' allegations insufficient to meet Rule 8's pleading standard, *see Iqbal*, 129 S. Ct. at 1940, but a review of the Investigator's Brochure demonstrates that those allegations are simply false: Juno did warn the investigators of the risks associated with participation in the ROCKET Trial. *See, e.g.*, Investigator's Brochure at 26-50; *see also Associated Builders, Inc. v. Ala. Power Co*., 505 F.2d 97, 100 (5th Cir. 1974) ("Conclusory allegations and unwarranted deductions of fact are not admitted as true, . . . especially when such conclusions are contradicted by facts disclosed by a document appended to the complaint."). Because Juno does not owe a duty to warn Ms. Holland (as discussed *supra*), Plaintiffs have failed to allege sufficient facts to state a plausible negligent marketing claim.

C. Plaintiffs Fail to Sufficiently Allege Negligent Misrepresentation (Count 7).

"To recover for negligent misrepresentation, the plaintiff must prove that: (1) the defendant made the representation in the course of business or in a transaction in which it has a pecuniary interest; (2) the defendant supplied false information for the guidance of others in their business; (3) the defendant did not exercise reasonable care or competence in obtaining or communicating the information; and (4) the plaintiff suffered pecuniary loss by justifiably relying on the representation." *Milestone Props., Inc. v. Federated Metals Corp*., 867 S.W.2d 113, 118 n. 6 (Tex. App.—Austin 1993, no writ). "When claims for fraud and negligent misrepresentation are based on the same set of alleged facts, Rule 9(b)'s heightened pleading standard applies." *McCall v. Genentech, Inc.*, 2011 WL 2312280, at *3 (N.D. Tex. June 9, 2011) (citation omitted). Here, Plaintiffs' claim for negligent misrepresentation and their fraud-based claims arise out of the same information provided to Ms. Holland in the Informed Consent document.

Plaintiffs allege that "[t]hrough the Informed Consent, which . . . contained information about the severity and prevalence of the side effects of JCAR015 provided by Juno, Juno

negligently gave, through its investigator, false information to Maty for her guidance in deciding whether to participate in the ROCKET Trial and upon which she reasonably and justifiably relied." Am. Compl. at ¶ 105 (emphasis added). But, as the Plaintiffs concede, the investigator—and not Juno—made the alleged representations through the Informed Consent. As such, Plaintiffs have failed to allege any specific representation that Juno made to Ms. Holland (or to the investigators), and how such representation is false. *See Guardian Underwriters Reassurance Ltd. v. Thompson*, 2004 U.S. Dist. LEXIS 862, at *11 (N.D. Tex. Jan. 26, 2004) ("For a negligent misrepresentation cause of action to lie in Texas, the defendant must make affirmative misrepresentations." (emphasis added)). Because Plaintiffs fail to specifically identify the representation that Juno made, or facts demonstrating that such representation was false—and because they fail to meet the requirements of Rule 9(b)—Plaintiffs' claim for negligent misrepresentation should be dismissed.

IV. Plaintiffs Do Not State a Claim for Fraud or Fraudulent Concealment (Count 4).

"The elements of fraud are: (1) a material misrepresentation was made; (2) the representation was false; (3) when the representation was made, the speaker knew it was false or made the statement recklessly without any knowledge of the truth; (4) the speaker made the representation with the intent that the other party should act on it; (5) the party acted in reliance on the representation; and (6) the party thereby suffered injury." *Tex. Integrated Conveyor Sys. v. Innovative Conveyor Concepts*, 300 S.W.3d 348, 366 (Tex. App.—Dallas 2009, pet. denied). Similarly, "[f]or fraudulent concealment to apply, the plaintiff must prove the defendant: '(1) had actual knowledge of the wrong; (2) had a fixed purpose to conceal the wrong; and (3) did conceal the wrong from the plaintiff.'" *Doe v. St. Stephen's Episcopal Sch*., 382 Fed.Appx. 386, 390 (5th Cir. 2010) (quoting *Quigley v. Bennett*, 256 S.W.3d 356, 360–61 (Tex. App.—San Antonio 2008, no pet.) (citing *Shah v. Moss*, 67 S.W.3d 836, 841 (Tex. 2001))).

Here, Plaintiffs' allegations of fraud and fraudulent concealment, which are unaffected by their new allegations, are combined into one count and rely on the same conclusory statement: "The Informed Consent omitted and withheld [] material information from Maty and affirmatively misrepresented the dangers of the ROCKET Trial and JCAR015." Am. Compl. at ¶ 102. Plaintiffs further allege that Ms. Holland acted in reliance on the information in the Informed Consent document when "deciding whether to participate in the ROCKET Trial" and that the "fraudulent representations of Juno, and its fraudulent concealment of material information, caused Maty's injuries and death." *Id*.

Plaintiffs' allegations fall far short of the pleading standards of Rule 9(b), as they do not provide "the 'who, what, when, where, and how' required under Rule 9(b)." *Tchuruk*, 291 F.3d at 350. Plaintiffs do not specify the "material information" that supposedly was withheld from Ms. Holland, nor the information that Juno allegedly "affirmatively misrepresented." Am. Compl. at ¶ 102. This failure, alone, is fatal to Plaintiffs' claims. *See also BP Am. Prod. Co. v. Marshall*, 342 S.W.3d 59, 67 (Tex. 2011) ("A party asserting fraudulent concealment must establish an underlying wrong, and that 'the defendant actually knew the plaintiff was in fact wronged, and concealed that fact to deceive the plaintiff.'" (citations omitted)); *AT&T Corp. v. Rylander*, 2 S.W.3d 546, 557 (Tex. App.—Austin 1999, pet. denied) ("Fraudulent concealment requires either the active suppression of truth or the failure to disclose when there is a duty to speak.").

But even more simply, Plaintiffs got the "who" wrong; because even if Plaintiffs had properly plead fraud-based allegations (and they did not), the Informed Consent demonstrates that the speaker of any alleged false representation was the trial investigators, not Juno. *See generally* Informed Consent; *see also* Am. Compl. ¶ 57 (alleging that MD Anderson staff obtained Ms. Holland's Informed Consent). Since it is apparent on the face of the Informed Consent (Exhibit 1

to the Amended Complaint) that Juno did not provide the Informed Consent to Ms. Holland, the fraud-based claims must fail. *See Associated Builders*, 505 F.2d at 100 ("Conclusory allegations and unwarranted deductions of fact are not admitted as true, . . . especially when such conclusions are contradicted by facts disclosed by a document appended to the complaint.").

Moreover, since Juno did not approve or provide the Informed Consent document to Ms. Holland, Plaintiffs cannot plead the requisite scienter of Juno. *See Melder v. Morris*, 27 F.3d 1097, 1102 (5th Cir. 1994) ("Because the complaint does not set forth specific facts to support an inference of fraudulent intent, dismissal under Rule 9(b) is appropriate."). Because Plaintiffs' fraud-based claims rely solely upon the Informed Consent, which Plaintiffs concede was approved and provided to Ms. Holland by a third party, the Court should dismiss these claims against Juno with prejudice.

V. Plaintiffs Do Not Allege a Valid Claim for Breach of Warranty (Count 8).

Similarly, Plaintiffs' breach of warranty claim (unchanged by their new allegations) is based solely on the information provided in the Informed Consent document: "Through the Informed Consent, Juno made express affirmations of fact regarding the ROCKET Trial and JCAR015. . . . [which] were a part of the basis of the bargain, . . . [and] Maty relied upon Juno's affirmations of fact in choosing to participate in the ROCKET Trial." Am. Compl. ¶ 106 (emphasis added). As discussed above, Juno was not a party to that document. Simply put, Juno made no statement to Ms. Holland. Therefore, Plaintiffs' breach of warranty claim fails as a matter of law. *See, e.g.*, *Berge Helene Ltd. v. GE Oil & Gas, Inc*., 896 F. Supp. 2d 582, 604 (S.D. Tex. 2012) ("To recover for breach of express warranty, a plaintiff must prove, inter alia, that the defendant made an express affirmation of fact or promise." (citations omitted)).[13]

[13] In addition, Plaintiffs fail to plead specific facts to support their bare legal conclusions. For example, the Plaintiffs do not identify what "express affirmations of fact regarding the ROCKET Trial and

VI. Plaintiffs' Request for Exemplary Damages Should Be Stricken in Its Entirety.

Plaintiffs allege that they are entitled to exemplary damages because "[t]he wrongful acts and/or omissions of Juno described [in the Amended Complaint] were committed intentionally, knowingly, maliciously, wantonly and willfully, and in conscious disregard of the well-established rights of Maty and Plaintiffs." Am. Compl. ¶ 108. Exemplary damages are a remedy and not a cause of action and should be stricken. *See Sulzer Carbomedics v. Oregon Cardio–Devices, Inc*., 257 F.3d 449, 461 (5th Cir. 2001); *Travelers Indem. Co. v. Fuller*, 892 S.W.2d 848, 852 (Tex. 1995). Plaintiffs seek exemplary damages pursuant to two separate sections of the Texas Code: §§ 41.003(a) and 71.009. *See* Am. Compl. ¶ 108. Furthermore, Plaintiffs allege that because "Juno's conduct constitutes a violation of Section 32.46 of the Texas Penal Code, exemplary damages in this action are not subject to the statutory cap." *Id*. (emphasis added).

As to Plaintiffs' individual claims pursuant to § 71.009, Article XVI, section 26 of the Constitution of the State of Texas, which governs the recovery of punitive damages in wrongful death actions, explicitly prohibits parents of decedents from recovering punitive damages on wrongful death claims. *See* Tex. Const. art. XVI, § 26. "It is well established that this provision defines the class of persons who are entitled to recover punitive damages for wrongful death; parents of the deceased . . . are not included in article XVI, § 26 and are therefore unable to recover punitive damages." *Gen. Chem. Corp. v. De La Lastra*, 852 S.W.2d 916, 923 (Tex. 1993) (emphasis added) (citation omitted). Therefore, the Court should strike the request for punitive damages as to Plaintiffs' individual claims pursuant to § 71.009 with prejudice.

JCAR015" Juno allegedly provided and Ms. Holland allegedly relied upon. Am. Compl. ¶ 106. Moreover, Plaintiffs do not specify how "[t]he ROCKET Trial and JCAR015 failed to comply with Juno's affirmations of fact contained in the Informed Consent." *Id*.

As to Plaintiffs' claims under § 41.003(a), as discussed *supra*, Plaintiffs have failed to state a plausible fraud claim against Juno for various reasons. Plaintiffs do not allege any facts demonstrating that Juno acted with malice. *See* Tex. Civ. Prac. & Rem. Code § 41.001(7) (defining "malice" as "a specific intent by the defendant to cause substantial injury or harm to the claimant"). Nor do Plaintiffs allege any facts to support a claim that Juno was grossly negligent. *See id.* § 41.001(11) (defining "gross negligence" as "an act or omission: (A) which when viewed objectively from the standpoint of the actor at the time of its occurrence involves an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and (B) of which the actor has actual, subjective awareness of the risk involved, but nevertheless proceeds with conscious indifference to the rights, safety, or welfare of others" (emphasis added)); *see also Exxon Mobil Corp. v. Altimore*, 256 S.W.3d 415, 425 (Tex. App.—Houston [14th Dist.] 2008, no pet.) ("[E]vidence of simple negligence is not evidence of gross negligence[,]" and thus cannot support an exemplary-damages award). Thus, the Court should strike Plaintiffs' request for exemplary damages pursuant to § 41.003(a).

Finally, because Juno was not a party to the Informed Consent document, and because there are no factual allegations claiming that Juno was actually involved in obtaining Ms. Holland's signature on the Informed Consent, Plaintiffs cannot seek uncapped damages under Section 32.46 of the Penal Code.

CONCLUSION

Based on the foregoing reasons, this Court should dismiss Plaintiffs' claims against Juno in their entirety. Further, because this is Plaintiffs' second attempt to replead all of the counts in their complaint, dismissal should be with prejudice.

Dated: October 22, 2018

Respectfully submitted,

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REQUEST FOR ORAL ARGUMENT

Pursuant to Section 6 of the Court's Procedures, Juno requests oral argument on its Motion to Dismiss Plaintiffs' Amended Complaint. Given the importance of the issues raised and the intricacies of the relevant case law, Juno believes that the Court and the parties would benefit from argument.

/s/ J. Laurens Wilkes
J. Laurens Wilkes

CERTIFICATE OF SERVICE

I hereby certify that on the 22nd day of October 2018, pursuant to the Federal Rules, the foregoing was served through the Court's CM/ECF System, which will send a notice of electronic filing to all counsel of record.

/s/ J. Laurens Wilkes
J. Laurens Wilkes